UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

**MEMORANDUM**

Date: 12/18/2018

Subject: Efficacy Review for Sterilex Ultra Disinfectant Cleaner Solution 1,
EPA Reg. No. 63761-8 (DP Barcode: 448835, E-Submission: 32134)

From: Samantha Collins
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Kristen Willis, Team Leader
Product Science Branch
Antimicrobials Division (7510P)
Date signed: 12/17/2018

To: Terria Northern / Zeno Bain
Regulatory Management Branch
Antimicrobials Division (7510P)

Applicant: Sterilex LLC
111 Lake Front Drive
Hunt Valley, MD 21030

**Formulation from the Label:**

| Active Ingredient(s) | % by wt. |
|---|---|
| n-Alkyl (C12 68%, C14 32%) dimethyl ethylbenzyl ammonium chloride | 3.0% |
| n-Alkyl (C14 60%, C16 30%, C12 5%, C18 5% dimethyl benzyl ammonium chloride | 3.0% |
| Hydrogen Peroxide (35%) | 6.3% |
| Other Ingredients | 87.7% |
| Total | 100.00% |

## I BACKGROUND

**Product Description (as packaged, as applied):** Liquid Concentrate

**Submission type:** Amendment

**Currently registered efficacy claim(s):** Disinfectant (bactericidal, virucidal, fungicidal), non-food contact sanitizer, and fungistat/mildewstat liquid concentrate product for hard, non-porous surfaces at varying contact times.

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**Requested action(s):** Addition of virucidal, biofilm, and emerging viral pathogen claims

**Documents considered in this review:**

- Letter from applicant to EPA dated September 6, 2018
- Emerging Viral Pathogen Letter dated November 9, 2018
- Data Matrix (EPA Form 8570-35)
- 5 efficacy studies (MRID 50673201 – 50673205, 49809105 and study ID GLP2037 no MRID)
- Proposed label dated 11/19/2018
- Confidential Statement of Formula (EPA Form 8670-4) dated 03/11/2016

## II PROPOSED DIRECTIONS FOR USE

**"GENERAL ONE STEP DISINFECTION AND CLEANING DIRECTIONS FOR HARD, NON-POROUS SURFACES**

Sterilex Ultra Disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution, is a one-step, cleaner and hospital-use disinfectant at 12.8 - 16.0 fl. oz. [378.5 – 473.2 ml] of Sterilex Ultra Disinfectant Cleaner Solution 1 and 12.8 – 16.0 [378.5 – 473.2 ml] fl. oz. of Sterilex Ultra Activator Solution per gallon [3.79 L] of water (1:1:10 – 1:1:8), or equivalent use dilution. [If high foam is desired, refer to High Foam Application Instructions.] Bactericidal according to the current AOAC Use-Dilution Test Method modified in the presence of 400 ppm hard water plus organic soil against:"

"APPLICATION INSTRUCTIONS:

To clean and disinfect in one step, remove gross [filth] [soil] from all areas, articles and surfaces to be disinfected using a pre-clean, pre-flush, or pre-scrape and, if necessary, presoak. Mix 12.8 - 16.0 fl. oz. [378.5 – 473.2 ml] of Sterilex Ultra Disinfectant Cleaner Solution 1 and 12.8 - 16.0 fl. oz. [378.5 – 473.2 ml] of Sterilex Ultra Activator Solution per gallon [3.79 L] of water. Thoroughly wet surfaces by pouring, wiping, brushing, scrubbing, foaming, spraying with a coarse trigger sprayer, sponging, using a clean in place (CIP) system, pumping it through the system, drawing it through the system, mopping or immersion. For sprayer applications, use a coarse pump or trigger sprayer. Spray 6-9 inches [15-22 cm] from surface. [If high foam is desired, refer to High Foam Application Instructions.] Do not breathe spray. Allow surfaces to remain wet for at least 10 minutes. Rinse all food contact surfaces thoroughly with a potable water rinse. Use product within 8 hours of mixing Sterilex Ultra Disinfectant Cleaner Solution 1 and Sterilex Ultra Activator Solution. [For initial start-up, repeat on all surfaces for [3] [3-5] consecutive {nights, treatments}]. [For routine maintenance applications treat all surfaces 1x/week, or as needed to maintain environmental counts.]

**[TOUGH][HEAVY DUTY] [SOIL] [INANIMATE SCUM] [INANIMATE MATERIAL] REMOVAL APPLICATION INSTRUCTIONS**

Preclean surfaces per the Precleaning Instructions. Mix 64.0 fl. oz. [1892.7 ml] of Sterilex Ultra Disinfectant Cleaner Solution 1 and 64.0 fl. oz. [1892.7 ml] of Sterilex Ultra Activator Solution per gallon [3.79 L] of water (1:1:2), or equivalent use dilution. Thoroughly wet surfaces by pouring, wiping, brushing, scrubbing, spraying, sponging, mopping, or immersion. Allow surfaces to remain wet for at least 10 minutes. Do not breathe spray. Rinse all food contact surfaces thoroughly with

a potable water rinse.  Use product within 8 hours of mixing Sterilex Ultra Disinfectant Cleaner Solution 1 and Sterilex Ultra Activator Solution. For a more concentrated option, prepare a 1:1 solution by mixing equal parts Sterilex Ultra Disinfectant Cleaner Solution 1 and Sterilex Ultra Activator Solution. Do not use Ultra Soft Metal Activator at the 1:1 or 1:1:2 application rate."

**"Kills Biofilm Bacteria [on] [in] [*insert hard, non-porous use site*]**

Sterilex Ultra Disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution, effectively penetrates biofilm and kills the following biofilm bacteria:

[*Pseudomonas aeruginosa* (*Pseudomonas*) [ATCC# 15442]]

[*Staphylococcus aureus* (*Staph*) [ATCC# 6538]]

APPLICATION INSTRUCTIONS:

Apply Sterilex Ultra Disinfectant Cleaner Solution 1 and Sterilex Ultra Activator Solution as a disinfectant, per the [Tough][Heavy Duty][Soil] [Inanimate Scum] [Inanimate Material] Removal Application Instructions. Use product within 8 hours of mixing Sterilex Ultra Disinfectant Cleaner Solution 1 and Sterilex Ultra Activator Solution."

## III STUDY SUMMARIES

| 1. | MRID | 50673201 | Study Completion Date: | 08/06/2018 |
|---|---|---|---|---|
| **Study Objective** | | Disinfectant, virucidal | | |
| **Testing Lab; Lab Study ID** | | Microbac, 971-102 | | |
| **Test organism(s)**<br>**☒ 1 ☐ 2 ☐ 3 ☐ 4+** | | New Castle Disease Virus, Strain: Lasota, Source: Charles River Laboratory | | |
| **Indicator Cell Culture** | | Vero, ATCC CCL-81 | | |
| **Test Method** | | Virucidal Hard-Surface Efficacy Test | | |
| **Application Method** | | Liquid concentrate | | |
| **Test Substance Preparation** | **Name/ID** | Sterilex Ultra Activator Solution | | |
| | **Lots**<br>**☐ 1 ☒ 2 ☐ 3** | RS1-189A, RS1-188B | | |
| | **Preparation** | Tested concentration: Nominal<br>Dilution: 1:1:10 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +10 parts Diluent)<br>Diluent: 400 ppm AOAC Hard Water | | |
| **Soil load** | | 5% fetal bovine serum | | |
| **Carrier type, # per lot** | | Glass petri dish, 1 per lot | | |
| **Test conditions** | | **Contact time** | 9-min 45-sec | **Temp** 21°C **RH** 45.4-46% |
| **Neutralizer** | | Sephacryl gel filtration | | |
| **Reviewer comments** | | | | |

| 2. | MRID | 50673203 | Study Completion Date: | 05/08/2018 |
|---|---|---|---|---|
| **Study Objective** | | Biofilm | | |
| **Testing Lab; Lab Study ID** | | Microchem, GLP1910 | | |
| **Test organism(s)**<br>**☒ 1 ☐ 2 ☐ 3 ☐ 4+** | | Pseudomonas aeruginosa (ATCC 15442) | | |
| **Test Method** | | Evaluation of Disinfectant Efficacy against a Biofilm - Single Tube Method | | |
| **Application Method** | | Liquid concentrate | | |
| **Test Substance Preparation** | **Name/ID** | Sterilex Ultra Activator Solution | | |
| | **Lots**<br>**☐ 1 ☐ 2 ☒ 3** | RS1-188A, RS1-188B, RS1-189A | | |
| | **Preparation** | Tested concentration: Nominal<br>Dilution: 1:1:2 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +2 parts Diluent)<br>Diluent: 400 ppm AOAC Hard Water | | |
| **Soil load** | | N/A | | |
| **Carrier type, # per lot** | | Glass coupon carriers, 5 | | |
| **Test conditions** | | **Contact time** | 9-min 45-sec | **Temp** 21°C **RH** N/A |
| **Neutralizer** | | 2X Dey/Engley Broth supplemented to contain 5.0% Tween 80 and 5.0% Catalase (76.0 ml) | | |
| **Reviewer comments**<br>(i.e. protocol deviations, etc) | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **3.** | **MRID** | 50673204 | **Study Completion Date:** | | | 05/25/2018 | |
| **Study Objective** | | Biofilm | | | | | |
| **Testing Lab; Lab Study ID** | | Microchem, GLP1914 | | | | | |
| **Test organism(s)**<br>**☒ 1 ☐ 2 ☐ 3 ☐ 4+** | | Staphylococcus aureus (ATCC 6538) | | | | | |
| **Test Method** | | Evaluation of Disinfectant Efficacy against a Biofilm - Single Tube Method | | | | | |
| **Application Method** | | Liquid concentrate | | | | | |
| **Test Substance Preparation** | **Name/ID** | Sterilex Ultra Activator Solution | | | | | |
| | **Lots**<br>**☐ 1 ☐ 2 ☒ 3** | RS1-188A, RS1-188B, RS1-189A | | | | | |
| | **Preparation** | Tested concentration: Nominal<br>Dilution: 1:1:2 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +2 parts Diluent)<br>Diluent: 400 ppm AOAC Hard Water | | | | | |
| **Soil load** | | N/A | | | | | |
| **Carrier type, # per lot** | | Glass coupon carriers, 5 | | | | | |
| **Test conditions** | | **Contact time** | 9-min 50-sec | **Temp** | 21°C | **RH** | N/A |
| **Neutralizer** | | 2X Dey/Engley Broth supplemented to contain 5.0% Tween 80 and 5.0% Catalase (76.0 ml) | | | | | |
| **Reviewer comments**<br>(i.e. protocol deviations, etc) | | | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **4.** | **MRID** | 50673205 | **Study Completion Date:** | | | 02/15/2018 | |
| **Study Objective** | | Disinfectant, virucidal | | | | | |
| **Testing Lab; Lab Study ID** | | Accuratus, A24854 | | | | | |
| **Test organism(s)**<br>**☒ 1 ☐ 2 ☐ 3 ☐ 4+** | | Porcine Respiratory & Reproductive Syndrome (PRRS) virus, University of Kentucky, Strain NVSL | | | | | |
| **Indicator Cell Culture** | | MARC-145 cells | | | | | |
| **Test Method** | | Virucidal Hard-Surface Efficacy Test | | | | | |
| **Application Method** | | Liquid concentrate | | | | | |
| **Test Substance Preparation** | **Name/ID** | Sterilex Disinfectant Cleaner Solution 1 and Sterilex Ultra Activator Solution | | | | | |
| | **Lots**<br>**☐ 1 ☒ 2 ☐ 3** | RS1-188B, RS1-189A | | | | | |
| | **Preparation** | Tested concentration: Nominal<br>Dilution: 1:1:10 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +10 parts Diluent)<br>Diluent: 400 ppm AOAC Hard Water | | | | | |
| **Soil load** | | 5% fetal bovine serum | | | | | |
| **Carrier type, # per lot** | | Glass petri dish, 1 per lot | | | | | |
| **Test conditions** | | **Contact time** | 9-min | **Temp** | 20°C | **RH** | N/A |
| **Neutralizer** | | Letheen Broth supplemented with 0.1% Sodium Thiosulfate,1.0% Tween 80, and 1% Catalase | | | | | |
| **Reviewer comments** | | cytotoxicity control was performed with spray application. | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **5.** | **MRID** | N/A | **Study Completion Date:** | | | 11/19/2018 | |
| **Study Objective** | | Disinfectant, additional bacteria | | | | | |
| **Testing Lab; Lab Study ID** | | Microchem, GLP2037 | | | | | |
| **Test organism(s)**<br>**☒ 1 ☐ 2 ☐ 3 ☐ 4+** | | Cronobacter sakazakii (ATCC 29004) | | | | | |
| **Test Method** | | AOAC Use-Dilution Method | | | | | |
| **Application Method** | | Liquid concentrate | | | | | |
| **Test Substance Preparation** | **Name/ID** | Sterilex Ultra Activator Solution | | | | | |
| | **Lots**<br>**☐ 1 ☐ 2 ☒ 3** | RS1-188B, RS1-188A | | | | | |
| | **Preparation** | Tested concentration: Nominal<br>Dilution: 1:1:10 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +10 parts Diluent)<br>Diluent: 400 ppm AOAC Hard Water | | | | | |
| **Soil load** | | 5% | | | | | |
| **Carrier type, # per lot** | | stainless steel penicylinder carriers, 10 | | | | | |
| **Test conditions** | | **Contact time** | 9-min | **Temp** | 20°C | **RH** | N/A |
| **Neutralizer** | | Letheen Broth additionally supplemented to contain 0.1% Catalase | | | | | |
| **Reviewer comments**<br>(i.e. protocol deviations, etc) | | | | | | | |

## IV STUDY RESULTS

**Disinfection – Virucidal Efficacy**

| **MRID** | **Organism** | **Description** | **Results** | | **Dried Virus Control ($Log_{10}$ $TCID_{50}$/carrier)** |
|---|---|---|---|---|---|
| | | | RS1-188B | RS1-189A | |
| *9-minute 45-second contact time, 1:1:10 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +10 parts Diluent of 400 ppm AOAC Hard Water, 5% soil load* | | | | | |
| 50673201 | New Castle Disease Virus, Strain: Lasota, Source: Charles River Laboratory | $10^{-3}$ dilution | Cytotoxicity | Cytotoxicity | 7.10 |
| | | $10^{-4}$ to $10^{-7}$ dilution | Complete inactivation | Complete inactivation | |
| | | $Log_{10}$ $TCID_{50}$/carrier | ≤3.10 | ≤3.10 | |
| | | Log Reduction | ≥4.00 | ≥4.00 | |
| *9-minute contact time, 1:1:10 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +10 parts Diluent of 400 ppm AOAC Hard Water, 5% soil load* | | | | | |
| 50673205 | Porcine Respiratory & Reproductive Syndrome (PRRS) virus, University of Kentucky, Strain NVSL | $10^{-1}$ dilution | Cytotoxicity | Cytotoxicity | 5.50 |
| | | $10^{-2}$ to $10^{-8}$ dilution | Complete inactivation | Complete inactivation | |
| | | $Log_{10}$ $TCID_{50}$/carrier | ≤1.50 | ≤1.50 | |
| | | Log Reduction | ≥4.00 | ≥4.00 | |

**Disinfection – Biofilm**

| MRID | Organism | $Log_{10}$ Reduction | | | Average $log_{10}$ CFU/Carrier |
|---|---|---|---|---|---|
| | | **Batch** RS1-188A | **Batch** RS1-188B | **Batch** RS1-189A | |
| *9-minute 45-second contact time, 1:1:2 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +2 parts Diluent of 400 ppm AOAC Hard Water)* | | | | | |
| **50638403** (03/23/18) | *Pseudomonas aeruginosa* (ATCC 154421) | ≥6.96 | | | 8.68 |
| (03/29/18) | | | ≥7.58 | | 8.07 |
| (03/30/18) | | | | ≥8.52 | 8.52 |
| **50638404** (04/05/18) | Staphylococcus aureus (ATCC 6538) | ≥6.34 | - | - | 7.91 |
| (05/03/18) | | - | ≥6.14 | - | 8.41 |
| (05/04/18) | | - | - | ≥6.09 | 8.41 |

**Disinfection – Additional Bacteria**

| MRID | Organism | $Log_{10}$ Reduction | | Average $log_{10}$ CFU/Carrier |
|---|---|---|---|---|
| | | **Batch** RS1-188A | **Batch** RS1-188B | |
| *9-minute 45-second contact time, 1:1:10 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +10 parts Diluent of 400 ppm AOAC Hard Water), 5% soil load* | | | | |
| **50638403** (11/14/18) | Cronobacter sakazakii (ATCC 29004) | 0/10 | 0/10 | 4.01 |

## V STUDY CONCLUSIONS

| MRID | Claim | Surface Type | Application Method(s) and Dilution | Contact Time | Soil load | Diluent | Organism(s) | Data support tested conditions? |
|---|---|---|---|---|---|---|---|---|
| **50673201** | Disinfectant Virucidal | Hard, non-porous surfaces | Use-dilution | 9-minutes 45-seconds | 5% | 1:1:10 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +10 parts Diluent 400 ppm AOAC hard water) | • New Castle Disease Virus, Strain: Lasota, Source: Charles River Laboratory | **Yes** |
| **50673205** | | | | 9-minutes | | | • Porcine Respiratory & Reproductive Syndrome virus, University of Kentucky, Strain NVSL | |
| **50673203** | Disinfectant Biofilm | Hard, non-porous surfaces | Use-dilution | 9-minutes 45-seconds | N/A | 1:1:2 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +2 parts Diluent400 ppm AOAC hard water) | • Pseudomonas aeruginosa (ATCC 15442) | **No** |
| **50673204** | | | | 9-minutes 50-seconds | | | • Staphylococcus aureus (ATCC 6538) | |
| **Not Yet Assigned** | Disinfectant Additional Bacteria | Hard, non-porous surfaces | Use-dilution | 9-minutes | 5% | 1:1:10 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +10 parts | • Cronobacter sakazakii (ATCC 29004) | **Yes** |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | Diluent 400 ppm AOAC hard water) | | |
| **49809105**<br><br>**49809107** | Emerging Viral Pathogen | Hard, non-porous surfaces | Use-dilution | 9-minutes | 5% | 1:1:10 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +10 parts Diluent 400 ppm AOAC hard water) | • Feline calicivirus, Strain F-9, ATCC VR-782<br>• Human Rotavirus (Group A), Strain Wa (TC-Adapted), ATCC VR-2018 | **Yes** |

## VI LABEL COMMENTS

**Label 11/19/2018:**

1. The proposed label claims that the product, Sterilex Ultra Disinfectant Cleaner Solution, EPA Reg. No. 63761-8 is an effective dilutable use-dilution virucidal disinfectant (1:1:10 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +10 parts Diluent)) against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 10-minute contact time:

   New Castle Disease Virus, Strain: Lasota, Source: Charles River Laboratory
   Porcine Respiratory & Reproductive Syndrome (PRRS) virus, University of Kentucky, Strain NVSL

   These claims are **acceptable** as they are supported by the submitted data

2. The proposed label claims that the product, Sterilex Ultra Disinfectant Cleaner Solution, EPA Reg. No. 63761-8 is an effective dilutable use-dilution Biofilm disinfectant (1:1:2 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +2 parts Diluent)) against the following on hard, non-porous surfaces in the presence of no organic soil for a 10-minute contact time:

   Staphylococcus aureus (ATCC 6538)
   Pseudomonas aeruginosa (ATCC 15442)

   These claims are **not acceptable** as they are not supported by the submitted data. Testing was conductedat the nominal concentration according to the proposed label dated 11/19/2018. Testing should be conducted at the lower certified limit (LCL) according to the label.

   To make the claim acceptable, the registrant may revise the dilution rate on the label to support testing at the LCL. The acceptable range above the LCL concentration for the quat is at or below 5.757% and at or below 6.05% for hydrogen peroxide. The label dilution rate may be revised to a 1:1:1 dilution ratio or a 1:1 dilution ratio for the biofilm claim or the claim should be removed from the label.

3. The proposed label claims that the product, for Sterilex Ultra Disinfectant Cleaner Solution, EPA Reg. No. 63761-8 is an effective dilutable use-dilution additional bacteria disinfectant (1:1:10 (1 part Disinfectant Cleaner Solution 1 + 1 part Activator Solution +10 parts Diluent)) against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 10-minute contact time:

   Cronobacter sakazakii (ATCC 29004)

   This claim is **acceptable** as it is supported by the submitted data

4. The proposed label claims that the product, Sterilex Ultra Disinfectant Cleaner Solution, EPA Reg. No. 63761-8 qualifies for the following emerging viral pathogens claims as described in the letter from the applicant to EPA dated November 9, 2018:

| *For an emerging viral pathogen that is a/an…* | *…follow the directions for use for the following organisms on the label:* |
|---|---|
| Enveloped virus | Rotavirus<br>Feline calicivirus |
| Large, non-enveloped virus | Feline calicivirus |

These claims are **acceptable** as they are supported by the cited data.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

-Enveloped Viruses

-Large Non-Enveloped Viruses

On page 17 of the proposed label, remove “Include Adenoviridae, Reoviridae, and Papillomaviridea” and “Includes Arenaviridae, Bornaviridae, Bunyaviridae, Coronaviridae, Filoviridae, Flaviviridae, Hepadnaviridae, Herpesviridae, Orthomyxoviridae, Paramyxoviridae, Poxviridae, Retroviridae, Rhabdoviridae, and Togaviridae” listed in the table under the “Large Non-Enveloped Virus Families” and “Enveloped Virus Families”.

5. Make the following changes to the proposed label:
    a. On page 9, revise the biofilm directions for use to specify a 1:1:1 dilution ratio or a 1:1 dilution ratio on the label for the biofilm claim or remove all biofilm claims from the label.
    b. On page 4 of the proposed label,
        i. remove the term “common” from the claim “common food borne pathogens”. In addition, remove the claim “eliminates” from as data did not demonstrate complete kill. Finally, remove brackets around the referenced pathogens, as this is not optional language, or include a reference notation to corresponding microorganisms in the use directions list on page 9.
        ii. remove references to an entire genus of bacteria such as “Listeria”, “Salmonella”, “Strep”, Staph” and “Pseudomonas”, These should be

revised to include the species name of the organism (ie. Listeria monocytogenes).

c. Qualify “exteriors” for “Individual quick freezing (IQF) freezers” and “ice making machines” On page 5 of the proposed label,
    i. revise label language to “removes** non-public health biofilm from [dental unit water] [animal drinking] [animal water] lines” and “suppresses formation of non-public health biofilm in [dental unit water] [animal drinking] [animal water]” as these are non-public health use sites and should be indicated as such to avoid misleading user.
    ii. remove the claim “Reduces potential repopulation of biofilm bacteria” as this implies residual activity and may be false or misleading to the user.
    iii. Remove “This product [meets][proven] biofilm efficacy performance standards” and “Proven to meet biofilm efficacy performance standards” as these imply agency endorsement.
    iv. Add the “*” qualifier to bacteria in the claim “Kills biofilm bacteria on non-food contact surfaces”
    v. Remove or further clarify “harborage niches”
    vi. Remove the claims “Clean. Disinfect. Protect” and “Protects against germs on hard, nonporous surfaces” as these imply protection from disease.
d. On page 6 of the proposed label
    i. Remove or qualify “Staphylocidal”, “Psuedomonacidal”, “Salmonellacideal” and “Listericidal” as these imply efficacy against the entire genus of bacteria.
    ii. Revise the claim “[Prevents][cross-contamination][spread of germs][in high traffic areas]” to “Reduces cross contamination on treated surfaces in high traffic areas”. Similarly revise the claim “Helps prevent the spread of [the flu][animal][avian] viruses* [in food plant animal health facilities” to “helps reduce the spread of [flu] [animal] [avian] viruses* on treated surfaces”.
    iii. Revise the claim “Helps prevent cross contamination on treated surfaces” to “Helps reduce cross contamination on treated surfaces”.
    iv. Qualify claims for use on freezer and chillers with external surfaces.
    v. remove the term “common” from the claim “common household germs”. Additionally, revise the “5 minute” contact time claim to “10 minutes”, as bacteria and a general “germ” claim have a 10 minute contact time.
    vi. remove the term “highly” from the claim “highly effective, economical and convenient germicide” as this implies heightened efficacy.
    vii. Remove the claim “is an effective aid in preventing many diseases of bacterial and viral origin”. The product can claim to kill microorganisms substantiated by data; however, a product may not claim prevention or protection from disease.
e. On page 7 of the proposed label,
    i. The claim “(Optional step)” for pre-cleaning instructions must include “(optional step for general one-step disinfection and non-food contact sanitization)” as pre-cleaning is required for food contact sanitization and biofilm disinfection.
f. On page 9 of the proposed label,
    i. Biofilm application instructions should indicate that the high foam application is not applicable to the biofilm kill claim.

ii. Remove “Ultra High Foam Additive may be added to mixed solution to enhance foam”. No confirmatory data were submitted to demonstrate efficacy using a chemical foaming agent.
iii. Registrant must specify that a mechanical foaming device should be used to produce the foam.

g. On page 10 and 11 of the proposed label, remove all claims of “Control of non-public health, vegetative, spore-forming bacteria”. Claims of kill or control of spore forming bacteria must be substantiated by data and are not applicable to non-public health use sites. Registrant may claim “controls food spoilage non-public health microorganisms”; however, the addition of specific species, especially spore-form bacteria, is not acceptable.
h. On page 13 of the proposed label, revise label language to “non-public health biofilm removal in animal drinking lines” and “remove non-public health biofilms found in tanks...” as these are non-public health use sites and should be indicated as such to avoid misleading user.
i. On the proposed label, under the headings “DISINFECTION AND SANITIZATION IN REFRIGERATED TRUCKS” and “DISINFECTION AND SANITIZATION OF SPIRAL FREEZERS, COOLING UNITS, COOLING TUNNELS, EVAPORATIVE CONDENSERS, INDIVIDUAL QUICK FREEZING (IQF) FREEZERS, AND OTHER COIL SURFACES”, indicate that surfaces must be at room temperature prior to disinfection or sanitization.
j. On page 18, 19, 20, and 21 of the proposed label, add “non-public health” to all biofilm claims made for non-public health use sites to avoid misleading user.